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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/695,178 | 10/28/2003 | J. Daniel Raulerson | Med-0065 | 4287 |

33941 7590 01/11/2006

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EXAMINER

AHMED, AAMER S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3763

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/695,178

Applicant(s)

RAULERSON ET AL.

Examiner

Aamer S. Ahmed

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>01/26/04 04/26/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS 09/16/04 10/20/04</u> . |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of claims 1-28 in the reply filed on 12/09/2005 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-8, 10-24, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Ash et al U.S. Patent Number 5,947,953.

In regards to claim 1, Ash et al discloses a multiple catheter assembly (10), comprising a first catheter (26) having a first proximal end region (50), a first distal end region (48) terminating in a first distal tip (64), and an outer surface defining at least a first lumen extending longitudinally therethrough between a first distal and a first proximal opening (see figure 1); a second catheter (30) having a second proximal end region (54), a second distal end region (52) terminating in a second distal tip (68), and a second outer surface defining at least a second lumen extending longitudinally therethrough between a second distal and a second proximal opening, wherein the first lumen and the second lumens are independent from each other for facilitating simultaneous flow in opposite directions, and wherein the outer surfaces of the first and second catheters are releasably joined for allowing the first and second distal tips and first

and second proximal end regions to be at least partially longitudinally split from each other (col. 3 line 15 and see figure 1 and 3a); and

In regards to claims 2 and 4, Ash et al discloses that the device further comprises a hub (24) releasably attached to each of the proximal end regions of the first and second catheters, wherein the hub is longitudinally translatable along the proximal end regions of the first and second catheters; and wherein the hub comprises a distal end adapted to juxtapose the first lumen against the second lumen and a proximal end adapted to separate the first and second lumens; and wherein the hub is releasably securable to a patient (see figure 2).

In regards to claims 5-8 and 10 Ash et al teaches an ingrowth cuff (56) disposed externally of the first and second lumens between the distal end region and the proximal end region of each of the first and second lumens; and wherein the hub (24) is longitudinally translatable between the proximal end regions of the first and second lumens and the ingrowth cuff (56); and wherein the assembly further comprises a first extension tube (113) releasably connected to the first proximal end region of the first catheter (26) and a second extension tube (111) releasably connected to the second proximal end region of the second catheter (30); and wherein the first and second catheters are releasably joined by a splittable bond (46) extending between the outer surface of the first catheter and the outer surface of the second catheter; and wherein each of the first and second catheters comprise a generally semi-circular cross-section, wherein the first catheter comprises a generally flat first side surface, and wherein the second catheter comprises a generally flat second side surface juxtaposed against the first flat side surface (see figure 4F).

In regards to claims 11-14, Ash et al discloses the catheter device wherein the proximal end regions of each of the first and second lumens comprise a generally circular cross section (see figure 4F) and wherein splittable bond (46) extends longitudinally between the generally flat first side surface of the first catheter and the generally flat second side surface of the second catheter, and wherein the splittable bond has a cross-sectional length significantly smaller than an outer diameter of said multiple catheter assembly as measured transversely across said multiple catheter assembly (see Figure 4E).

In regards to claims 15 Ash et al discloses, a method for inserting a multiple catheter assembly into an area of a body to be catheterized, comprising making an incision near the area to be catheterized (col. 12 line 58); providing a multiple catheter assembly comprising a first catheter (26) having a first proximal end region (50), a first distal end (48) region terminating in a first distal tip (64), and a first outer surface defining at least a first longitudinally extending lumen; and a second catheter (30) having a second proximal end (54), a distal end region (52) terminating in a distal tip (68), and a second outer surface defining at least a second longitudinally extending lumen; wherein the outer surfaces of each of the first and second catheters are releasably joined and each of the first and second lumens are independent from each other for facilitating simultaneous flow in opposite directions (see claim 1), wherein the outer surfaces of each of the first and second catheters are releasably joined for allowing each of the first and second distal tips and first and second proximal ends to be at least partially longitudinally split from each other (col. 13 line 10); at least partially separating the first and second distal end regions of the first and second catheters from each other; and inserting the first

and second distal end regions of the first and second catheters in juxtaposed relation to each other through the incision and into the area to be catheterized (col. 13 line 27).

In regards to claim 16-21, Ash teaches the device comprising at least partially separating the proximal end regions of the first and second catheters and wherein further comprising inserting a tearable sheath into the area to be catheterized prior to inserting the distal end regions of the first and second catheters through the sheath and into the area to be catheterized (col. 13 line 1); and further comprising removing the sheath after the distal end regions of the first and second catheters are in the area to be catheterized (col. 13 line 32); and wherein attaching a tunneling device to the first and second proximal end regions of the first and second catheters (col. 13 line 65); and further comprising subcutaneously tunneling (col. 13 line 50) the proximal end regions of the first and second catheters; and removing the tunneling device from the first and second proximal end regions of the first and second catheters (col. 14 line 8).

In regards to claims 22-24 and 27-28, Ash et al discloses that the proximal end regions of the first and second catheters are at least partially separated (see figure 3a); and further comprising closing the incision after distal end regions are inserted in the area to be catheterized (col.13 line 38); releasably attaching a hub to the proximal end regions of the first and second catheters; and further releasably connecting the hub to the patient (col. 12 line 32) and wherein releasably connecting a first extension (113) tube to the first proximal end region of the first catheter and releasably connecting a second extension tube (111) to the second proximal end region of the second catheter.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3, 9, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ash et al in view of Brenner U.S. Patent Number 6,497,681. Ash et al. disclose the device and method as described above in reference to claims 1 and 24. Ash et al fails to disclose that the hub is longitudinally translatable along; nor that the hub is adapted to separate the first and second lumens.

In regards to claim 3, Brenner discloses a similar device and method in which the hub (20) is adapted to separate the first and second lumens (col. 2 line 25).

In regards to claims 25 and 26, Brenner teaches, a distal end of the hub is adapted to juxtapose the first and second lumens against each other and a proximal end of the hub is adapted to separate the first and second lumens (col. 2 line 25) the method further comprising placing the first and second lumens together into the distal end of the hub; at least partially separating the proximal end regions of the first and second catheters; placing the proximal end

Art Unit: 3763

regions of each of the first and second catheters into the proximal end of the hub, whereby the proximal end of the hub separates the first and second catheters (col. 4 line 36) and wherein longitudinally translating the hub along the proximal end regions of the first and second catheters to a desired location along the proximal end regions of the first and second catheters (see figures 5 and 6).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Ash et al by incorporating the translatable hub of the type taught by Brenner in order to stabilize or hold an elongated intravascular instrument at a desired position within a patient's body to facilitate the removal of a tearable or otherwise splittable introducer, without disturbing that pacing lead or other elongated intravascular instrument (see abstract).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ash et al in view of Butler et al U.S. Patent Number 6,758,854. Ash et al discloses the invention as described above in reference to claim 1, but fails to disclose that the splittable bond comprises an adhesive. Butler et al describes a similar device in which the two plastic materials are joined using an adhesive (col. 14 line 24). It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Ash et al by incorporating the adhesive bond of the type taught by Butler et al in order to join the two catheters (col. 14 line 24).

Double Patenting

Claims 1-6 and 8-28 of this application conflict with claim 1-6 and 8-28 of Application No. 10/974267. 37 CFR 1.78(b) provides that when two or more applications filed by the same

Art Unit: 3763

applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Double Patenting

Claims 2-6 and 8-28 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-6 and 8-28 of copending Application No. 10/974267. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim 2-6 and 8-28 directed to the same invention as that of claim 1-6, 8-28 of commonly assigned application N. 10/974267. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/497267.

Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one having ordinary skill in the art to modify the device

as disclosed in claim 1 of the instant application by incorporating the extensions later disclosed in claim 7 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 20050277862 A1 Anand, PJ
US 5160323 A Andrew; Daniel E.
US 6190349 B1 Ash; Stephen R. et al.
US 20010025134 A1 Bon, Edwin et al.
US 6758854 B1 Butler; William et al.
US 3297030 A CZORNY VASIL P et al.
US 3981297 A Dunn; Karl L. et al.
US 5141497 A Erskine; Timothy J.
US 5951518 A Licata; Michael J. et al.
US 4997424 A Little; Richard L.
US 3550591 A MACGREGOR DOUGLAS
US 20020107475 A1 Maginot, Thomas J.
US 5053023 A Martin; Geoffrey S.
US 4925452 A Melinyshyn; Lev et al.
US 6796991 B2 Nardeo; Mahase
US 5807311 A Palestrant; Aubrey M.
US 6001079 A Pourchez; Thierry
WO 2004041347 A1 RAULERSON, J DANIEL et al.
US 20040097903 A1 Raulerson, J. Daniel
US 5045065 A Raulerson; J. Daniel
US 5346471 A Raulerson; J. Daniel
US 5944732 A Raulerson; J. Daniel et al.
US 20030153898 A1 Schon, Donald A. et al.
US 20040054321 A1 Schon, Donald A. et al.

Art Unit: 3763


US 20040059314 A1 Schon, Donald A. et al.
US 6695832 B2 Schon; Donald A. et al.
US 5718692 A Schon; Donald et al.
US 20040176739 A1 Stephens, John et al.
US 20020099327 A1 Wilson, Jon S. et al.
US 5707358 A Wright; John T. M.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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